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29 March 2006

HUESCHEN AND SAGE

Dated: 29 March 2006

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Applicant : Bruno PFEIFFER, Yves-Michel GINOT, Gérard COQUEREL, and Stéphane BEILLES

Serial No. : 10/792,355

Filed : March 3, 2004

Title : α-CRYSTALLINE FORM OF PERINDOPRIL TERT-BUTYLAMINE SALT

Art Unit : 1626

Examiner : Rei Tsang SHIAO, Esq.

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Honorable Commissioner for Patents
PO Box 1450
Alexandria, VA 22313

RESPONSE AND ELECTION UNDER 37 CFR §§ 1.111 AND 1.142
AND
TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR
§§ 1.97 AND 1.98

Sir:

Responsive to the Office Action, a Restriction Requirement, dated December 1, 2005, **as to which the period for response has been extended by three (3)**

04/04/2006 MAHMED1 00000019 10792355

01 FC:1806 180.00 OP

04/04/2006 MAHMED1 00000019 10792355

02 FC:1253 1020.00 OP

months by payment of the appropriate fee, it is the position of the Office that the application pertains to a plurality of patentably distinct inventions. The Applicants **traverse** this conclusion on the grounds that a chemist would not find the instant invention to involve structurally distinct inventions. Absent contradictory evidence that those skilled in the art would find the instant invention to consist of multiple inventions, it is submitted that the Office Requirement is not substantiated.

The Applicants respectfully submit that **Group I** is drawn to compositions comprising a **single**, α -crystalline form of perindopril tert-butylamine salt, **Group II** is drawn to a process of making the **single**, α -crystalline form of perindopril tert-butylamine salt, and **Group III** is drawn to a method of using the **single**, α -crystalline form of perindopril tert-butylamine salt. It is, however, the position of the Office that "each of Groups I-III is distinct and independent product, process of making or methods of use one from the other..." and that "...because of the plethora of classes and subclasses in each of the Groups, a serious burden is imposed on the examiner to perform a complete search of the defined areas."

The applicants **traverse** this conclusion on the grounds that the disclosure demonstrates the criticality of the instant process (**Group II**) with respect to yield and purity of the resulting **single**, α -crystalline form of perindopril tert-butylamine. Moreover, the Applicants assert that the method claims of **Group III** are also part of the claimed invention. An important characteristic of the substances of **Group I** is their pharmacological activity, which activity is claimed in the form of method claims. Absent contradictory evidence that those skilled in the art would find the instant invention to consist of multiple inventions, it is submitted that the Office Requirement is not substantiated. Reconsideration and withdrawal are respectfully solicited.

Nonetheless, in the absence of a favorable decision on the above-noted request for reconsideration and in an effort to advance the prosecution of the instant application, the Applicants elect **with traverse** to prosecute the invention of **Group I** (Claims 14, 23, and 25-26), drawn to compounds of formula (I), of the Restriction Requirement. Applicants designate the species of Example 1, α -crystalline form of perindopril tert-butylamine salt (i.e., the single compound of instant Claim 14), as

representative of **Group I**. Moreover, the Applicants respectfully request that the Examiner include at least one method of treatment claim from **Group III** for simultaneous prosecution with the substance claims of **Group I**, which inclusion is the well settled practice of the Office. The Applicants hereby designate the claim to treatment of *cardiovascular disease* for such examination.

Absent a favorable decision upon reconsideration of the Restriction Requirement, the Examiner may withdraw the non-elected subject matter, without prejudice to its rejoinder during later examination and/or prosecution in a Divisional Application.

Finally, with the instant Response, the Applicants also submit an Information Disclosure Statement which, it is respectfully submitted, should materially advance and accelerate the prosecution of the above-identified application. It is respectfully requested that the information be expressly considered during the prosecution of this application and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

As will be noted, this Information Disclosure Statement calls a number of references, which might be considered relevant, to the attention of the Examiner. The fact that these are in fact "Prior Art" is, however, not admitted.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR § 1.98 and the Examiner is respectfully requested to consider the listed references.

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Accordingly, entry of the present Election into the record of this application and favorable action on the merits thereof, are respectfully solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

By:



G. PATRICK SAGE

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